

REMARKS/ARGUMENTS

Claim 1 is the only pending claim in this application. In the present response, Claim 1 has been amended in order to more clearly recite applicants' claimed composition. The amendments to claim 1 are completely supported by the application as originally filed and thus there is no issue of new matter.

Applicants additionally propose herein for addition to the application new claims 3-9 (claim 2 having been previously canceled). The new claims are all also supported by the as-filed application and thus, they also raise no issue of new matter.

Entry of the new claims, as well as the amendments to claim 1, is therefore respectfully solicited. Upon such entry, claim 1 as amended and claims 2-9 (new) will be pending in this application.

Information Disclosure Statement

The Office Action states that the Information Disclosure Statement filed December 1, 2004 with the application fails to comply with 37 C.F.R. §1.98(a)(2) which requires submission of a legible copy of each cited foreign patent document. The Examiner, therefore, has crossed off the last four (foreign) references listed on the form headed "Applicant's Art Citation" and has added the notation "not submitted" to the form. One cited foreign reference was not crossed off. It has an English-language equivalent, i.e., a U.S. patent, and therefore it was made of record by the Examiner. The Examiner states further in the Office Action that the Information Disclosure Statement has been placed in the application file, but the information referred to therein (which applicants take to mean the references that were crossed off) has not been considered.

Submitted herewith, in response, are legible copies of the four references crossed off by the Examiner in the previously filed citation, accompanied by English-language abstracts where available. The subject references are, furthermore, listed on the form accompanying this Response and the Examiner is respectfully requested to make them of record in this application by initialing and dating the citations thereof on the attached form and returning a copy of the completed form to applicant's representative with the next communication from the Office concerning this application.

Claim Rejection Under 35 U.S.C. §112

Claim 1 is rejected under 35 U.S.C. §112, second paragraph, as being allegedly indefinite for the reasons set forth in the Office Action. In response to the rejection, the claim has been amended to more clearly recite applicants' composition. No new matter has been added by the amendments.

Applicants submit that, as amended, claim 1 is believed to meet all of the requirements for particularly pointing out and distinctly claiming the invention under 35 U.S.C. §112. As such, the Examiner is respectfully requested to reconsider and withdraw the §112 rejection.

Claim Rejection Under 35 U.S.C. §103

Claim 1 is rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over the combination of EP 0780129 of Yamada, et al. in view of Griesbach et al. USP 6,875,754, JP 10025240 and Schmidt et al. USP 5,578,300. The rejection is respectfully traversed.

Claim 1 is directed to a an external medicine for treating atopic dermatitis and psoriasis vulgaris. The medicine is an aqueous solution comprising
0.025 to 0.5% by weight of the adrenocortical steroid;
0.2 to 30% by weight of the cyclodextrin;
0.5 to 55% by weight of a dextran or pullulan; and
0.5 to 55% by weight of each xyloglucan, trehalose, laminaran, krestin, and pectin.
The medicine further comprises, i.e., in addition to the aqueous solution described above, at least one grape sugar, mutan, lentinan, sodium chloride, and potassium chloride.

Applicants submit that as explained below, the references combined to reject claim 1 entirely fail to teach or even suggest the composition recited in the subject claim, whether those references are taken individually or in combination. Furthermore, as proposed new claims 3 & 4 depend from claim 1, they also contain all of the features recited in the subject claim and, as such, are believed to distinguish over the cited prior art for at least the same reasons as claim 1.

Turning first to the Yamada et al. reference, the Examiner's attention is respectfully drawn to the fact that the authors of the subject reference are the same two individuals named as co-inventors of the present application and invention. Applicants submit that the presently claimed composition, i.e., as recited in e.g., claim 1, represents an improvement over applicants' earlier work as described in the subject reference, which improvement is neither taught nor even

suggested by the disclosure contained in the reference. More particularly, claim 1 recites, *inter alia*, the presence in the claimed composition of from 0.5 to 55% by weight of each of xyloglucan, trehalose, laminaran, krestin and pectin which are blended, components which are not taught for inclusion in the formulation described in the subject reference. Furthermore, applicants' claim 1 additionally recites that the aqueous solution additionally comprises at least one grape sugar, mutan, lentinan, sodium chloride and potassium chloride, which is another aspect of the present invention that is not taught by the cited reference.

Applicants have, furthermore, surprisingly determined that the novel formulation recited in, e.g., claim 1 of the present application provides significantly improved results in the treatment of atopic dermatitis and psoriasis vulgaris when compared to the results obtained with a composition according to the Yamada reference. This result, then, supports a finding of non-obviousness with regard to the subject claim. The cited reference discloses an effective rate against atopic dermatitis that was only about 95% on average, whereas the rate obtained with regard to psoriasis vulgaris was only about 90% on average. In the case of the use of the presently claimed composition, however, as taught in the present application effective rates of around 99% were obtained. Claim 1 has, thus, been amended not only to recite the additional components noted above, but to additionally recite that the external medicine which is the subject of claim 1 is adopted for the treatment of, specifically, atopic dermatitis and psoriasis vulgaris, against which the presently claimed formulation provides particularly effective results. The reference, therefore, also does not even suggest the formulation recited in applicants' claim 1.

Turning next to Griesbach, the subject reference discloses a method of treating skin conditions or skin diseases which comprises a step of applying to the skin a solution including water soluble β -(1,3) glucans, which have intact β -(1,3) side chains that are free from repetitive β -(1,6) linkages, as active substances. The fact that the composition disclosed in the reference is lacking β -(1,6) linkages thus teaches away from the composition according to claim 1 since the xyloglucan and laminaran which are identified as required components of the presently claimed composition do contain such a β -(1,6) linkage.

Turning next to a discussion of the JP '240 reference, the applicant submits that what is disclosed therein is a bath powder. The reference teaches to utilize 30 to 50 g of the bath powder with 200 liters of hot water. It seems to applicants, therefore, that the composition recited in claim 1 is thus entirely distinguishable over the disclosure contained in the cited reference.

Furthermore, with regard to the Schmidt U.S. '300 patent, applicant submits that the subject reference discloses a method of treating allergic contact dermatitis which comprises a step of treating a patient with a formulation capable of inducing oxidative stress and a heat shock response so as to convert the allergic reaction of the allergic contact dermatitis into an irritant reaction. The method is carried out with the use of a formulation that comprises a hydrogen peroxide generating polymeric material comprising gelatin and pectin wherein the formulation, as noted above is used so as to induce an oxidative stress and obtain the heat shock response. The pectin component of the formulation according to Schmidt thus serves a completely different purpose from the purpose served by this material according to claim 1 of the present application.

As can be seen from the discussion above, therefore, none of the four references combined by the Examiner, when taken individually, teach or even suggest the composition recited in claim 1. Applicants recognize, of course, that the rejection is not based on the references as taken individually, but rather it is based upon the combined disclosures of the subject references. Applicants believe that they can say without contradiction that their earlier work, i.e., as disclosed in Yamada et al., represents the closest prior art to the presently claimed composition. The reference thus is the 'primary' reference in the cited combination. With regard to the secondary references, however, applicants submit that these references do not teach or even suggest to modify Yamada et al. to a composition as now recited in present claim 1. Griesbach, in fact, actually teaches away from the presently claimed formulation by teaching as a required component a material which is entirely lacking in β -(1,6) linkages. The JP '240 reference teaches to dissolve 30 to 50 grams of a bath powder in 200 liters of hot water. Again, the disclosure contained in JP '240 moves one no closer to the present invention than does the Griesbach reference. Finally, the U.S. Schmidt patent teaches to incorporate pectin for a purpose completely different than the material serves in the presently claimed composition. For the reasons above, therefore, even when the disclosure of all four of the cited references are combined, one still would not arrive at a formulation which is the same as, or which even suggests, the formulation as recited in applicants' claim 1.

For the reasons given, therefore, the Examiner is respectfully requested to reconsider and withdraw the rejection of claim 1. Furthermore, as noted above claims 3-4 depend from claim 1

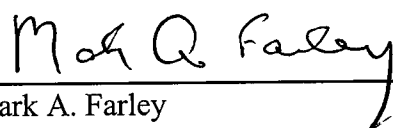
and, as such, they include all of the recitations found in the parent claim. Thus, claims 3 and 4 are believed to be distinguishable for the same reasons as claim 1.

Applicants turn, next to a discussion of proposed new claim 5 (written in independent form), as well as claims 6-9 (dependent on claim 5). Claim 5 is directed to a treatment method, using the external medicine as recited in, e.g., claim 1, for treating dermatitis. Applicants respectfully submit that the composition recited for use in the subject claim is believed to be both novel and unobvious over at least the references cited in the rejection of claim 1 for the reasons given above. Still further, applicants additionally direct the Examiner's attention to the fact that a claim essentially similar to claim 1 as now amended was found to exhibit both Novelty and an Inventive Step in the face of a rejection over the references listed in the International Search Report during the prosecution of the International application upon which the present application is based. This, then, is believed to provide even further evidence of the 'inventiveness' of the composition as recited in, e.g., claims 1 and 5. As claim 5 thus recites a 'use', i.e., in a method of treatment, for such novel and unobvious composition, both claim 5 and those claims which depend from that claim are believed to be both novel and non-obvious.

The Examiner is, therefore, respectfully requested to withdraw all of the objections and rejections set forth in the present Office Action and to, thus, issue a Notice of Allowance for all of applicants' pending claims.

THIS CORRESPONDENCE IS BEING
SUBMITTED ELECTRONICALLY
THROUGH THE PATENT AND
TRADEMARK OFFICE EFS FILING
SYSTEM ON November 4, 2008.

Respectfully submitted,



Mark A. Farley
Registration No.: 33,170
OSTROLENK, FABER, GERB & SOFFEN, LLP
1180 Avenue of the Americas
New York, New York 10036-8403
Telephone: (212) 382-0700

MAF:stb